



UNITED STATES PATENT AND TRADEMARK OFFICE

CL
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|----------------------------|-------------|----------------------|---------------------|------------------|--|
| 10/019,655 | 08/06/2002 | Steven E Rokita | 55859-024 | 5726 | |
| 23552 | 7590 | 06/27/2007 | EXAMINER | | |
| MERCHANT & GOULD PC | | RUSSEL, JEFFREY E | | | |
| P.O. BOX 2903 | | ART UNIT | | PAPER NUMBER | |
| MINNEAPOLIS, MN 55402-0903 | | 1654 | | | |
| | | MAIL DATE | | DELIVERY MODE | |
| | | 06/27/2007 | | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/019,655 | ROKITA ET AL. | |
| | Examiner | Art Unit | |
| | Jeffrey E. Russel | 1654 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 January 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 27-66 is/are pending in the application.
- 4a) Of the above claim(s) 40-42 and 60-64 is/are withdrawn from consideration.
- 5) Claim(s) 35 is/are allowed.
- 6) Claim(s) 27-34,37-39,43-59,65 and 66 is/are rejected.
- 7) Claim(s) 36 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 06 August 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

1. The election of species requirement set forth in the Office action mailed May 19, 2006 is hereby withdrawn. Search and examination has been extended to all of the species encompassed by the claims of the elected invention.

Because the compounds of formula I as set forth in instant claim 27 have been examined and found to be novel and unobvious over the prior art of record, method claims 37-39, 53-59, 65, and 66, which are limited to the use of the compounds of formula I, have been rejoined with the elected invention and examined on the merits.

Claims 40-42 and 60-64 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 21, 2006.

Applicant's election with traverse of the invention of Group I, and the species compound A, in the reply filed on August 21, 2006 is acknowledged. The requirement is still deemed proper and is therefore made FINAL.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

2. The Sequence Listing filed September 25, 2005 (including the paper copy of the sequence listing and the statements re-submitted on January 4, 2007) is approved.

The preliminary amendment originally submitted on September 27, 2005 and re-submitted on January 4, 2007 has been entered.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-34, 37-39, 43-59, 65, and 66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

Art Unit: 1654

possession of the claimed invention. There is no original disclosure supporting the recitation in claims 27 and 32 that R can be a nitrogen-containing cationic group. The original disclosure is limited to R comprising at least one C_b group linked to a nitrogen atom (see, e.g., page 6 and originally-filed claim 1). The new claim limitation is broader than the original disclosure in that the new claim limitation no longer requires the cationic group to comprise at least one C_b group. Applicants have not indicated where the original disclosure of the invention supports the new claim limitation.

4. Claims 32, 45, and 48-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 32, the variable L is used in structures A and B, but is not defined in the claim. It is unclear whether “the protein” at claim 45, line 2, refers to the protein ligand of claim 44 or to the complexed protein of claim 43. It is unclear whether “the protein” at claim 50, line 2, refers to the protein ligand of claim 49 or to the complexed protein of claim 48.

5. Claims 29 and 36 are objected to because of the following informalities: At claim 29, line 2, “compound” should be inserted after “fluorescent”. At claim 36, line 1, the two beginning parentheses at the end of the line are unmatched. Appropriate correction is required.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1654

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

7. Claims 32, 33, 48, 49, and 52 are rejected under 35 U.S.C. 103(a) as being obvious over Burrows et al (U.S. Patent No. 5,272,056). Burrows et al teach compound 9 at column 5, lines 60-67. (Note that the certificate of correction shows that the "C" atoms in Burrows et al's compound 9 should be "O" atoms.) In the compound, M is preferably nickel. See column 11, line 39. Compound 9 of Burrows et al corresponds to Applicants' formula A in which R'' is R' which is hydrogen. The compound of Burrows et al can be conjugated to substituents which are capable of binding to DNA or nucleotides, including certain proteins or protein fragments. See column 10, lines 34-39; and column 11, lines 4-28. The substituents capable of binding to DNA or nucleotides correspond to Applicants' detectable labels. Burrows et al do not specifically teach or exemplify compound 9 conjugated to a substituent which is capable of binding to DNA or nucleotides. It would have been obvious to one of ordinary skill in the art at the time

Art Unit: 1654

Applicants' invention was made to conjugate a substituent capable of binding to DNA or nucleotides to compound 9 of Burrows et al, because Burrows et al teach that compound 9 can be substituted, because Burrows et al teach that substituents capable of binding to DNA or nucleotides are particularly important substituent groups, and because conjugation of these particularly important substituent groups with only the expected gain of function is *prima facie* obvious. Compound 9 when modified with a substituent capable of binding to DNA or nucleotides as suggested by Burrows et al, and when contacted with DNA or nucleotides, will form the oligonucleotide complex as claimed by Applicants in claim 48. When the substituent capable of binding to DNA or nucleotides is a protein or protein fragment as suggested by Burrows, the protein or protein fragment corresponds to the protein ligand recited in instant claim 49, and to the epitope recited in instant claim 52.

8. Applicant's arguments filed January 4, 2007 have been fully considered but they are not persuasive.

Burrows et al (U.S. Patent No. 5,272,056) is not applied against claim 27 or the claims dependent upon it. Compound 9 of Burrows et al does not comprise or suggest the N(R')(G) which is required by formula I of instant claim 27.

Burrows et al is applied against claims 32 and 33. The examiner agrees that the compounds of Burrows et al, including compound 9, are not conjugated to biotin. However, the rejected claims are not required to be conjugated to biotin. As to conjugation to ligands in general, Burrows et al suggest conjugation to substituents capable of binding to DNA or nucleotides, which substituents correspond to Applicants' generic "L" groups. Applicants contend that the ligands of Burrows et al are neutral and their solubility is very low in aqueous

Art Unit: 1654

systems. However, Applicants' claims do not require the presence of charged ligands or of ligands which are soluble in aqueous systems. Patentability must be based upon claimed, not unclaimed, differences over the prior art. In any event, the ligands/substituents of Burrows et al are not necessarily neutral and/or insoluble in aqueous systems. See, e.g., column 11, lines 8-28. Applicants contend that Burrows et al do not foresee covalent attachment of a nickel complex and DNA. However, the rejected claims do not require covalent attachment of DNA to a nickel complex. Patentability must be based upon claimed, not unclaimed, differences over the prior art. In any event, Burrows et al do foresee such covalent attachment - see column 11, lines 9 and 17-19.

9. The Stemmler et al article (J. Am. Chem. Soc., Vol. 121, pages 6956-6957) is cited as art of interest, but is not deemed to teach or suggest the instant claimed invention. Note that compound 1 of the Stemmler et al article does not teach or suggest the G substituent required by Applicants' formula I, or the CH(R')C(O)NH₂ group required by Applicants' formula B. Compound II of Stemmler et al does not teach or suggest the N(R')(G) group required by Applicants' formula I, or the L substituent required by Applicants' formula A.

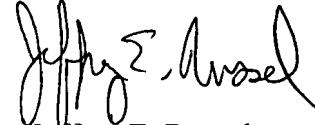
10. Claim 35 is allowed. Claim 36 would be allowable if rewritten or amended to overcome the claim objection set forth in this Office action. Claims 27-31, 37-39, 43-47, 53-59, 65, and 66 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, first and second paragraphs, and the claim objection set forth in this Office action. Claim 34, 50, 51 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, first and second paragraphs, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
June 19, 2007